

in FIG. 3) adapted to isolate the analyte from the sample of material is disposed within central housing 15.

[0051] After sample acquisition assembly 3 is introduced into opening 26A, and first fluid 9 is introduced into hollow shaft 7 of sample acquisition device 5, the eluted sample flows along the first flow path created by valve 14 in its sample preparation orientation. The eluted sample moves from first housing segment 16 through central housing segment 15 and to third housing segment 20. As the eluted sample flows through central housing segment 15, the eluted sample moves through capture medium 24 (shown in phantom in FIG. 3), which is disposed within central housing segment 15. Preferably, capture medium 24 is positioned and retained in such a way that fluid may pass over and through capture medium 24 while at the same time allowing capture medium 24 to capture and isolate the analyte from the sample of material. Examples of suitable capture media include, but are not limited to, beads, a porous membrane, a foam, a frit, a screen, or combinations thereof. The capture media may be coated with a ligand specific to the analyte, e.g., an antibody. In other embodiments, other means for isolating the analyte may be used. After the eluted sample moves through capture medium 24, the remainder of the eluted sample (minus the captured analyte), which are no longer necessary for the assay, flows to third housing segment 20. In this way, third housing segment 20 receives "waste". In some embodiments, an absorbent material is disposed in third housing segment 20 in order to retain the waste fluid in sufficient quantity in order to decrease the possibility that the waste fluid will move back into central housing segment 15 or another housing segment 16, 18, or 22 and contaminate the assay. In alternate embodiments, other means for retaining waste fluid are used.

[0052] After the analyte is isolated from the sample of material, the sample preparation stage is complete. Of course, in other embodiments, the assay may require additional sample preparation steps. After the waste fluid has flowed to third housing segment 20, sample acquisition assembly 3 may be removed and valve 14 may be actuated (e.g., rotated) from its sample preparation position to its testing position.

[0053] After valve 14 is in its testing position, second fluid 25 disposed in fourth housing segment 22 may be released and introduced into central housing segment 15. The exemplary second fluid 25 is a second buffer solution. Once again, the type of buffer solution that is to be incorporated into the assay is dependent upon many factors, including the analyte that apparatus 10 is configured to detect. In the exemplary embodiment, a frangible seal (not shown) is disposed in pathway 23 between fourth housing segment 22 and central housing segment 15. Valve 14 is configured to pressurize pathway 23 to break the frangible seal. This allows second fluid 25 to be selectively released from fourth housing segment 22. Second fluid 25 moves through capture medium 24 disposed in central housing segment 15 and releases at least some of the analyte from capture medium 24.

[0054] Prior to contacting testing device 30, any analyte that is present is placed in contact with a reagent adapted to react with the analyte in order for the indirect assay to run properly. Because the reagent is likely dehydrated in order to keep the reagent stable during storage of apparatus 10, second fluid 25 retained in third housing segment 22 may be used to hydrate the reagent, and reactivate it. In the exemplary embodiment, a dehydrated reagent is disposed within pathway 23 and is retained in a seal formed by the flexible material forming the housing segments 15, 16, 18, 20, and 22. When

fourth housing segment 22 is pressurized by valve 14, the seal containing the reagent is broken, similarly to the description of how an applied pressure to a fluid reservoir ruptures an adjacent barrier described in U.S. Patent Application Publication No. 2003/0214997, published on Nov. 20, 2003.

[0055] In alternate embodiments, the dehydrated reagent may be disposed within any suitable place within apparatus. For example, the dehydrated reagent may be disposed in fourth housing segment 22, where second fluid 25 and the dehydrated reagent are capable of being separated until the operator wishes the reagent to be hydrated. Alternatively, the reagent may also be disposed in central housing 15, pathway 19 between second housing segment 18 and central housing 15, or second housing segment 18.

[0056] After second fluid 25 releases at least some of the analyte from capture medium 24, second fluid 25 and the released analyte move into second housing segment 18 along the second flow path formed by valve 14. Where the reagent and analyte react depends on where the reagent is disposed. However, it is preferred that the analyte react with a reagent at some time prior to contacting the testing device because as previously stated, in an indirect assay, it is the reagent that reacts with the testing device. In the present invention, the analyte and reagent react in central housing segment 15. Apparatus 10 may be agitated in order to help the reagent and analyte react.

[0057] Disposed within second housing segment 18 is third fluid reservoir 28 (shown in phantom in FIG. 3) configured to receive second fluid 25 and the released analyte, testing device 30, and channel 32 connecting third fluid reservoir 28 to testing device 30. In the exemplary embodiment, channel 32 includes microfluidic elements for controlling the flow of fluid from third fluid reservoir 28 to testing device 30. Testing device 30 may require fluid to flow past it at or below a certain rate in order for the analyte or reagent in the fluid to react with testing device 30. In the case of the exemplary embodiment, an indirect assay is used, and so it is the reagent in the fluid that reacts with testing device 30. A plurality of microfluidic elements may help this regulate this fluid flow past testing device 30. In order to encourage fluid flow past testing device 30, absorbent material 34 may be positioned in second housing segment 18, where testing device 30 is positioned between channel 32 and absorbent material 34. Absorbent material 34 may help the fluid flow past testing device 30 by way of a wicking action.

[0058] Testing device 30 provides a visual indicium of whether the analyte is present in the sample of material collected with sample acquisition device 5, and in some embodiments, the test result indicates the quantity of analyte. In the exemplary embodiment, testing device 30 is a calorimetric sensor, which may include, for example, a polydimethylacetylene material, as described in U.S. Patent Application Publication No. 2004/0132217 A1, and U.S. Patent Application Ser. No. 60/636,993, filed on Dec. 17, 2004, both entitled, "COLORIMETRIC SENSORS CONSTRUCTED OF DIACETYLENE MATERIALS".

[0059] In the exemplary embodiment, a color of testing device 30 corresponds to a color-coding scheme. Testing device 30 may or may not provide a color change, depending upon whether the analyte is present in the sample of material. A user may view this color change through window 36 (shown in FIG. 3). The color change may also be graded in order to indicate the quantity of analyte present. The quantity of analyte may, for example, be indicated a color gradient